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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,297	12/08/2003	Jack W. Romano		2174

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EXAMINER	
BOGART, MICHAEL G	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,297	ROMANO ET AL.	
	Examiner	Art Unit	
	Michael G. Bogart	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4,17 and 18* is/are allowed.

6)☒ Claim(s) *5-16 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings dated 08 December 2003 are acceptable for examination purposes only. Upon allowance, new formal drawings will be required.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 5-14 and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldberg.

Regarding claims 5 and 6, Goldberg discloses a supply chain method comprising,

a) sealing a liquid (e.g., irrigation fluid, dialysate) in a container (not shown) by closing and sealing a container at manufacturing (col. 6, lines 3-22; col. 8, lines 1-8; col. 12, line 64-col. 13, line 27),

b) providing said liquid in said container at a point of consumption (col. 12, line 64-col. 13, line 27),

c) unsealing said container by removing said closure,

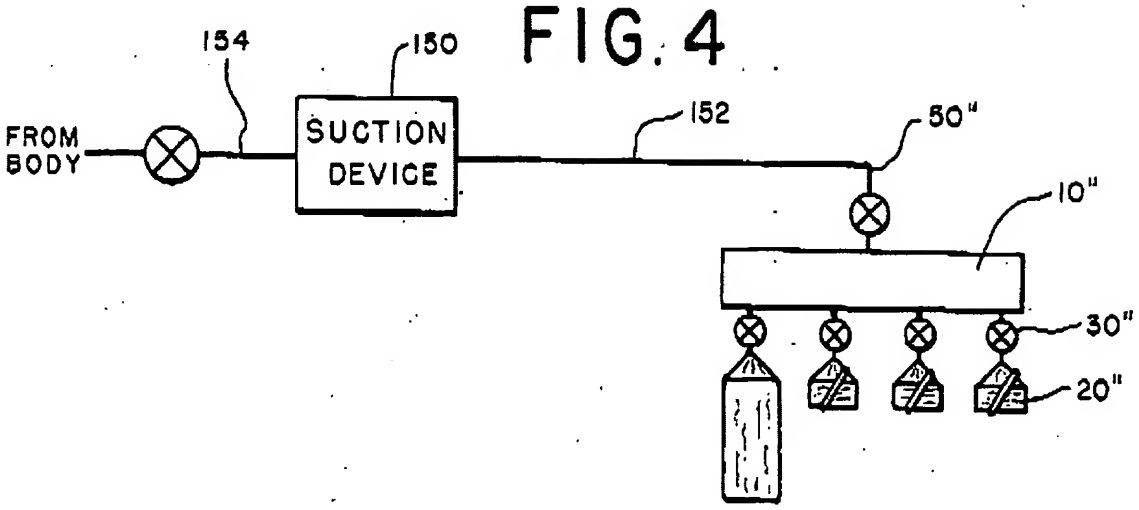
d) sealing a vacuum draw path (320, 330) with said container by coupling said path (320, 330) with a fluent material waste collection system (310) and said container,

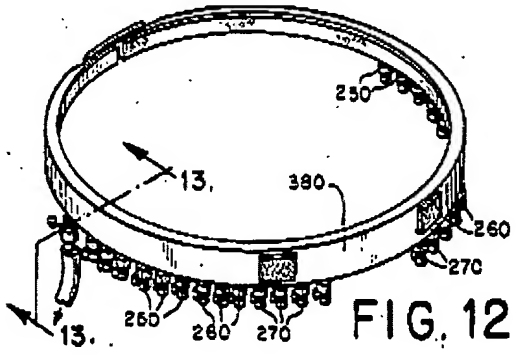
e) drawing said fluent material waste into said container,

f) unsealing said path by disconnecting said container from said vacuum draw path (320, 330) and said waste collection system (310),

g) sealing said container with a closure for containment and disposal of said fluent waste material (Abstract; col. 4, lines 16-50; col. 6, lines 37-48; col. 12, line 64-col. 13, line 27)(figures 4 and 12, infra).

It is noted that when the device is being used to output dialysate to a patient, line (320, 330) will at least be under a partial vacuum because the system is closed.





Given the context of the entire disclosure, and the emphasis on maintaining sterility of the system, it is at least implied that the fluid to be introduced into a human is sterile or aseptic. (see col. 6, lines 9-22). "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Regarding claims 7 and 8, Goldberg teaches that the containers are integrated into a waste collection system (fig. 4 & 12) and that the sterile fluid containers are recycled as waste containers (col. 3, line 51-col. 4, line 53; col. 12, line 64-col. 13, line 27).

Regarding claims 9-11, Goldberg teaches that the sterile fluid container (clean side of a supply)(20) is converted to a waist receptacle (dirty disposal side) in a disposal chain.

Regarding claim 12-14, Goldberg at least implies that by reusing supply containers of dialysate as collection containers that will reduce the amount of containers that contribute to garbage compared to using completely separate supply and collection containers, resulting in reduced waste and costs and increasing the useful lifetime of the supply containers (col. 12, line 64-col. 13, line 27).

Regarding claims 19-24, Goldberg teaches means (40) for sealing and/or unsealing a vacuum draw path.

Claims 15 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldberg as applied to claims 5-14 and 19-24 above, and further in view of Weiler *et al.* (US 4,178,976; hereinafter "Weiler") and Kawakami *et al.* (US 6,159,416 A; hereinafter "Kawakami").

Goldberg is silent as to the containers being made from biodegradable blow moldable materials.

Weiler teaches a dispensing container comprised of blowmoldable material (col. 4, lines 48-64).

Kawakami teaches blow moldable materials that are biodegrable.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to make the containers of Goldberg out of the blow moldable materials of Weiler and Kawakami in order to provide materials that are recognized in the art as suitable for this purpose and the added benefit of decomposing in landfills.

Allowable Subject Matter

Claims 4, 17 and 18 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The art of record does not teach or fairly suggest a supply chain method as described in detail in the rejection of claims 5-14 and 19-20, supra, adding the additional step of manufacturing the specific container structure claimed in subsection a) of claim 4, and further adding the step threadably connecting the container to the lid of a canister system.

Response to Arguments

Applicant's arguments filed 18 October 2006 have been fully considered but they are not persuasive.

Applicants assert that Goldberg fails to teach a supply chain method. This argument is not persuasive because the supply chain method is only recited in the preamble of the claims and does not set forth any structural elements or steps to be performed. It only recites what the method is used for. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). *See also Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553

(Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). MPEP § 2111.02 (II).

Additionally, Goldberg teaches manufacturing of the various components of the device (10, 20, 50)(col. 6, lines 3-22). Manufacturing of the device is a step in the supply chain of that device.

Applicants assert that Goldberg teaches a container that is manufactured in a dry condition, not filled with liquid. This argument is not persuasive because Goldberg teaches an embodiment where a pre-filled dialysate container (not shown) is used to introduce dialysate into port (250) and on to a peritoneal cavity under sterile conditions. After the dialysate container is drained, it is left connected to port (250)(col. 12, line 64-col. 13, line 35). Although the specification does not expressly disclose that the dialysate container is manufactured and maintained under sterile conditions, given the nature of the device and the specification as a whole, it is at least implied that they are to remain sterile and sealed to avoid infection of a patient. See *In re Preda,* supra. Also, as interpreted herein, the step of filling the dialysate containers is considered to be a step in its manufacture prior to its consumption by a patient. It is further implied that there is a step of unsealing the dialysate containers when it is attached to port (250) in order for it to drain into the port.

Applicants assert that the container does not have a valve. While this may be the case, it is at least implied that the dialysate container is sealed prior to use to maintain sterility.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Goldberg does

not teach a single sealed unit from the beginning) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants assert that there is no draw path at an input port. This argument is not persuasive because when line (320, 330) is in fluid communication with container and patient to provide dialysate, there is at least a partial vacuum as the system is closed.

Furthermore, when dialysate is removed, there is at least a vacuum draw path that brings used dialysate back into the container.

Applicants' arguments from pages 2-9 are centered on Goldberg as shown in the embodiment of figure 4. However, Goldberg teaches an embodiment in figure 12 that shows:

Pre-filled containers of dialysate that based on the reference as a whole, it as at least implied that it is sterile and sealed prior to use. The step of filling it is a part of the filled container's manufacturing process. It is attached and placed in fluid communication with port (250) on belt (380). It is at least implied that the container must be unsealed in order to provide such a connection. During consumption, dialysate flows from the container through port (250) into belt (380) and belt catheter to an indwelling catheter and into a peritoneal cavity. The system is closed so that there is at least a partial vacuum contributing to the drawing of fluid through this pathway. Later, used dialysate liquid is then drawn back into the container, the container is removed from the port and belt. It is at least implied that the container with used dialysate would be sealed as at this point is would be considered biohazardous waste.

Regarding this specific embodiment, applicants assert that Goldberg's belt is originally a sealed sterile unit with all of the valves being closed until after the dialysate container is attached. It is only removed after it has been drained and refilled via the same port. This is not distinguished from the invention as claimed, see the discussion of this embodiment in the preceding paragraph.

Applicants assert that Goldberg does not teach conversion of containers from a supply side to a dirty side and that there is not teaching of providing multiple uses for the containers. This argument is not persuasive because Goldberg at page 12, line 64-page 13, line 27 teaches an embodiment where the dialysate containers are used to provide sterile liquid, and then, to dispose of used waste liquid. This avoids the need for separate waste containers.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCB

Michael Bogart
22 March 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

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